FILED

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA ALEXANDRIA DIVISION

2012 APR -6 P 3:52

CLERK US DISTRICT COURT ALEXANDINA, VIRGINIA

Incyte Corporation
Experimental Station
Route 141 & Henry Clay Road
Building E336
Wilmington, DE 19880

Plaintiff,

٧.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office
Office of General Counsel,
United States Patent and Trademark Office,
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Rm. 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Case No. 1:12cv 380 LMB/JFA

COMPLAINT

Plaintiff, Incyte Corporation ("Incyte"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

- 1. This is an action by the assignee of United States Patent No. 8,034,953 ("the '953 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '953 patent be changed from 1,028 days to at least 1,166 days.
- 2. This action arises under 35 U.S.C. § 154 and the Administrative Procedures Act, 5 U.S.C. §§ 701-706.

JURISDICTION AND VENUE

- 3. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.
 - 4. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).
 - 5. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

THE PARTIES

- 6. Plaintiff Incyte is a corporation organized under the laws of Delaware, having a principal place of business at Experimental Station, Route 141 & Henry Clay Road, Building E336, Wilmington, Delaware 19880.
- 7. Defendant, the Honorable David J. Kappos ("Director"), is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("USPTO"), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the USPTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

BACKGROUND

- 8. Andrew P. Combs and Eddy W. Yue are the inventors of U.S. patent application number 11/430,441 ("the '441 application") entitled "Modulators of Indoleamine 2,3-Dioxygenase and Methods of Using the Same," which was issued as the '953 patent on October 11, 2011. The '953 patent is attached as Exhibit A.
- 9. Plaintiff Incyte is the assignee of the '953 patent, as evidenced by the assignment documents recorded in the USPTO.

- 10. Under 35 U.S.C. § 154(b), the Director of the USPTO must grant a patent term adjustment in accordance with the provisions of section 154(b), which states, in pertinent part, that "[t]he Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination." 35 U.S.C. § 154(b)(3)(D).
- 11. In determining patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the USPTO under 35 U.S.C. §§ 154(b)(l)(A), (B), and (C), as limited by the following: (i) any overlapping periods of USPTO delay as specified by 35 U.S.C. § 154(b)(2)(A); (ii) any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B); and (iii) any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).
- 12. The Director initially determined that the '953 patent is entitled to 1,026 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '953 patent reflecting that determination.
- 13. On December 9, 2011, in accordance with 37 C.F.R. § 1.705(d), Plaintiff filed an Application for Patent Term Adjustment ("Application for PTA") with the USPTO to request correction of the Director's patent term adjustment determination. Specifically, Plaintiff sought a reduction of the USPTO's calculation of applicant delay by 2 days and an increase of the USPTO's calculation of USPTO delay by 138 days. The Application for PTA is attached as Exhibit B.
- 14. On December 19, 2011, the USPTO issued a Decision On Request For Reconsideration Of Patent Term Adjustment And Notice Of Intent To Issue Certificate Of

Correction ("Decision") granting Plaintiff's request for a reduction of the USPTO's calculation of applicant delay by 2 days, but denying Plaintiff's request for an increase of the USPTO's calculation of USPTO delay by 138 days. The USPTO's Decision is attached as Exhibit C.

- 15. On January 19, 2012, Plaintiff filed a Response To Decision On Request For Reconsideration Of Patent Term Adjustment And Notice Of Intent To Issue Certificate Of Correction ("Response") requesting reconsideration of that portion of the Decision that denied Plaintiff's request. The Response is still pending before the USPTO and is attached as Exhibit D.
- 16. Title 35 U.S.C. § 154(b)(4)(A) provides that "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after grant of the patent." The Leahy-Smith America Invents Act recently changed the venue for actions brought under 35 U.S.C. § 154(b)(4)(A) to the Eastern District of Virginia.

CLAIM FOR RELIEF

- 17. The allegations of paragraphs 1-16 are incorporated in this claim for relief as if fully set forth.
- 18. The patent term adjustment for the '953 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth in the Decision, is 1,028 days. This determination is in error because the USPTO, and the Director acting in his official capacity, improperly calculated the length of the statutory delay period. As explained in the Response (Ex. D), the USPTO improperly calculated the length of the statutory delay period defined by 35 U.S.C. § 154(b)(l)(B) by subtracting from the delay period the number of days from the mailing of a Notice of Allowance until issuance (138 days).

19. The correct patent term adjustment for the '953 patent is 1,166 days (1,028 days plus 138 days).

20. Accordingly, the Director's determination that the '953 patent is entitled to only 1,028 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

PRAYER FOR RELIEF

Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '953 patent term from 1,028 days to 1,166 days and requiring the Director to extend the term of the '953 patent to reflect the 1,166-day patent term adjustment.

B. Granting such other and future relief as the nature of the case may admit or require and as may be just and equitable.

Dated: April 6, 2012

Respectfully Submitted,

Ahmed J. Davis (Va. Bar No. 43972)

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pending)

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